

second one-piece graft segment and the second one-piece graft segment can be deployed thereafter in a telescoping manner with respect to the first one-piece graft segment by advancing the catheter into a lumen formed when the first one-piece graft system is deployed and further withdrawing the sheath such that the second one-piece graft segment is deployed partially within the first one-piece graft segment, the first and second one-piece graft segments further including at least one stent segment; and

a transition element fixed to the inner portion, substantially between the first and second one-piece graft segments, the transition element having a smooth tapering diameter in the direction of the first one-piece graft segment to facilitate insertion of the second one-piece graft segment into the first one-piece graft segment after the first one-piece graft segment has been deployed.

REMARKS

In response to the Final Office Action mailed October 28, 2002, Applicants propose to amend their application and request reconsideration in view of the proposed amendments and the following remarks. In this amendment, claims 37 and 46 are proposed to be amended, no claims are proposed to be cancelled or added so that claims 37-46 remain pending. No new matter has been introduced.

Claims 37-45 were rejected as anticipated by U.S. Patent No. 6,123,722 to Fogarty et al. (Fogarty). This rejection is respectfully traversed.

U.S. Patent No. 6,123,722 to Fogarty et al. discloses stents and stent-grafts for the treatment of aneurysms. Specifically, Fogarty discloses prosthetic modules, which may be selectively combined to form a composite prosthesis. Also disclosed is a delivery catheter which comprises a tubular cover and a shaft coaxially positioned in the cover. The catheter also comprises a plurality of runners and a nosecone.

The present invention as claimed in amended independent claim 37 is directed to a graft system for repairing an abdominal aortic aneurysm. The system comprises a one-piece tubular graft component having a first end portion, a second end portion and a middle portion. The middle portion includes one or more independent gripping stents spaced apart from one another and secured to an inner surface of the one-piece graft component. And the cross-sectional area of the first and second end portion is greater than the cross-sectional area of the middle portion. The one-piece graft component tapers from the first and second end portions to the middle portion.

Anticipation exists only if all of the elements of the claimed invention are found in a system or method disclosed, expressly or inherently, in a single prior art reference. Therefore, if it can be shown that there is one difference between the claimed invention and what is disclosed in the single reference, there can be no anticipation.

Fogarty discloses stent grafts that are modular. It is specifically stated that modular sections of the prostheses may be selectively combined to form a composite prosthesis. In the present invention, as claimed in amended independent claim 37, the graft system comprises a one-piece component. In other words, a single structure. Fogarty fails to disclose or even remotely suggest "a one-piece" structure. In fact, Fogarty teaches away from this structure by disclosing multiple graft sections. Therefore, since Fogarty fails to disclose this element, there can be no anticipation. Accordingly, reconsideration and withdrawal of the rejection is respectfully requested.

Claim 46 was rejected as unpatentable over Fogarty in view of U.S. Patent No. 5,476,506 to Lunn. This rejection is respectfully traversed.

U.S. Patent No. 5,476,506 to Lunn discloses a graft for placement in a body passageway. The graft is designed such that it is longitudinally expandable and has end portions that are radially expandable. The walls of the central portion are provided with circumferential crimps and the walls of the end portions are provided with axially extending crimps. Lunn does not disclose stent elements.

The MPEP, in section 706.02(j), sets forth the basic criteria that must be met in order to establish a *prima facie* case of obviousness:

To establish a *prima facie* case of obviousness, three basic criteria must be met. First, there must be some suggestion or motivation, either in the references themselves or in the knowledge generally available to one of ordinary skill in the art, to modify the reference or to combine reference teachings. Second, there must be a reasonable expectation of success. Finally, the prior art reference (or references when combined) must teach or suggest all the claim limitations. The teaching or suggestion to make the claimed combination and the reasonable expectation of success must both be found in the prior art and not based on applicant's disclosure. *In re Vaeck*, 947 F.2d, 488, 20 USPQ2d 1438 (Fed.Cir. 1991). See MPEP § 2143 - § 2143.03 for decisions pertinent to each of these criteria.

The present invention as claimed in amended independent claim 46 is directed to a graft system for repairing an aneurysm in a vessel. The graft system comprises a delivery catheter having an outer sheath and an inner portion contained within a lumen formed by the outer sheath, first and second one-piece graft segments located in the delivery catheter between the inner portion and the

sheath, the first and second one-piece graft segments being formed of a material which expands from a radially contracted position to a radially expanded position when the sheath is withdrawn, the first and second one-piece graft segments being positioned in the delivery catheter in a non-overlapping manner such that the first one-piece graft segment may be deployed independently of the second one-piece graft segment and the second one-piece graft segment can be deployed thereafter in a telescoping manner with respect to the first one-piece graft segment by advancing the catheter into a lumen formed when the first one-piece graft system is deployed and further withdrawing the sheath such that the second one-piece graft segment is deployed partially within the first one-piece graft segment, the first and second one-piece graft segments further including at least one stent segment; and a transition element fixed to the inner portion, substantially between the first and second one-piece graft segments, the transition element having a smooth tapering diameter in the direction of the first one-piece graft segment to facilitate insertion of the second one-piece graft segment into the first one-piece graft segment after the first one-piece graft segment has been deployed.

Applicants respectfully submit that the cited prior art references, whether taken alone or in combination fail to disclose or suggest all of the claim limitations. Fogarty fails to disclose or suggest first and second one-piece graft segments. Lunn fails to disclose stent segments. Applicants also respectfully submit that there is simply no motivation or suggestion to modify the apparatus of Fogarty based on the

teachings of Lunn. Accordingly, reconsideration and withdrawal of the rejection is respectfully requested.

Applicants would be willing to interview the present case if the Examiner so desires.

The Amendment/Reply raises no new issues and places the application in form for allowance. Therefore, entry is proper and earnestly solicited.

Attached hereto is a marked-up version of the changes made to the claims by the current amendment. The attached pages are captioned "Version With Markings To Show Changes Made."

Respectfully submitted,



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Version With Markings To Show Changes Made

IN THE CLAIMS

Please amend the claims as follows:

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37. (Three Times Amended) A graft system for repairing an abdominal aortic aneurysm comprising [at least one integral, unitary] a one-piece tubular graft component having a first end portion, a second end portion, and a middle portion extending therebetween, the middle portion including one or more independent gripping stents spaced apart from one another and secured to an inner surface of the [integral] one-piece tubular graft component, wherein the cross-sectional areas of the first and second end portions is greater than the cross-sectional area of the middle portion and the one-piece graft component tapers from the first and second end portions to the middle portion.

46. (Twice Amended) A graft system for repairing an aneurysm in a vessel comprising:

a delivery catheter having an outer sheath and an inner portion contained within a lumen formed by the outer sheath;

first and second [integral, unitary] one-piece graft segments located in the delivery catheter between the inner portion and the sheath, the first and second one-piece graft segments being formed of a material which expands from a radially contracted position to a radially expanded position when the sheath is withdrawn, the first and second one-piece graft segments

being positioned in the delivery catheter in a non-overlapping manner such that the first one-piece graft segment may be deployed independently of the second one-piece graft segment and the second one-piece graft segment can be deployed thereafter in a telescoping manner with respect to the first one-piece graft segment by advancing the catheter into a lumen formed when the first one-piece graft system is deployed and further withdrawing the sheath such that the second one-piece graft segment is deployed partially within the first one-piece graft segment, the first and second one-piece graft segments further including at least one stent segment; and

a transition element fixed to the inner portion, substantially between the first and second one-piece graft segments, the transition element having a smooth tapering diameter in the direction of the first one-piece graft segment to facilitate insertion of the second one-piece graft segment into the first one-piece graft segment after the first one-piece graft segment has been deployed.